

REMARKS

Claims 1–8, and 42–52 are pending in this application. Applicants appreciate the thorough examination by the Examiner as evidenced by the Final Action mailed May 6, 2010. In response, Applicants submit the present amendment and respectfully request entry of the claim amendments presented herein in view of the accompanying RCE, and further consideration of the present application in view of this amendment and the remarks provided below.

Support for Claim Amendments

The amendments presented above have been made to recite particular features of the inventions so as to expedite the prosecution of the present application to allowance in accordance with the USPTO Patent Business Goals (65 Fed. Reg. 54603, September 8, 2000). These amendments do not represent an acquiescence or agreement with any of the outstanding rejections.

Claims 45–49 are amended herein to correct an inadvertent errors in claim numbering. Claims 1–8 and 42–44 are amended herein to more distinctly point out what Applicants regard as the invention. Claim 1 has been amended to incorporate the recitations of original claim 44 and claim 44 has been amended to be directed toward more particular embodiments of claim 1. Lastly, new claims 50–52 added herein are also directed toward more particular embodiments of claim 1. Support for these amendments may be found throughout the application, drawings and claims as originally filed, and more specifically at page 9, lines 18–20 and at page 11, lines 10–12 of the specification. The issues raised by the Examiner are addressed hereinbelow in the order in which they appear in the Final Action.

Claim Objections:

Claims 44–48 are objected to for informalities. Specifically, two claims have been inadvertently identified as claim 44. Applicants amend claims 45–49 herein to correct this error. In view of the foregoing, Applicants believe that this issue has been addressed. Nevertheless,

should any issues remain regarding this matter, Applicants respectfully solicit the Examiner for suggestions so as to bring this matter to a resolution.

Claim Rejections - 35 U.S.C. § 102

Items 4 and 5. Claims 1–4, 6 and 7 stand rejected under 35 U.S.C. 102(b) as being anticipated by Zhang et al. (1993) *Langmuir* 9:2337–2343 (“Zhang et al.”) and claims 1, 5 and 6 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Rudolf et al. (2002) *J. Magn. Res.* 155:45–56 (“Rudolf et al.”).

Applicants amend claim 1 herein, incorporating the recitations of previously presented claim 44 and to point out that the claimed subject matter is directed toward a composition comprising a zeolite and a pharmaceutical, nutraceutical or cosmetic carrier as set forth in previously presented claim 44, and amend claim 44 to further point out that said composition is contained in an airtight bag.

In that the claimed subject matter of previously presented claim 44 does not stand rejected on this basis, Applicants believe that the instant rejection has been rendered moot. Nonetheless, Applicants respectfully submit that neither Zhang et al. nor Rudolf et al. disclose all the elements of that which is instantly claimed, i.e., a composition comprising a zeolite and a pharmaceutical, nutraceutical or cosmetic carrier. In view of the foregoing, Applicants believe the instant claims are not anticipated by Zhang et al. or Rudolf et al., and respectfully request that the instant rejection be withdrawn.

Claim Rejections - 35 U.S.C. § 103

Item 9. Claim 8 and 42 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Zhang et al. as applied to claim 7 and in further view of U.S. Patent No. 5,492,883 (“Wu”). The Examiner submits that it would have been obvious to one of ordinary skill in the art at the time of the invention to utilize a binder as disclosed by Wu in the formation of a monolith as taught by Zhang et al. in order to make the invention as instantly claimed.

In view of the amendment to claim 1, Applicants submit that the disclosures of Zhang et al. do not teach all the elements of the composition as set forth in claim 7. Wu discusses improved zeolite structures, particularly cellular zeolite structures such as extruded honeycomb monoliths and methods of preparing the same using aqueous emulsions of silicone resins (*see*, col.2, lines 7–10) for use as molecular sieves. However, the disclosures of Wu do not cure the deficiencies in the disclosures of Zhang et al. for teaching a composition comprising the zeolite as claimed and a pharmaceutical, nutraceutical or cosmetic carrier. As such, Applicants submit that the disclosures of Zhang et al. and Wu, alone or in combination, do not teach all the elements of the composition as instantly claimed. In view of the foregoing, Applicants respectfully submit that the instant claims are patentable over Zhang et al. In further view of Wu, and respectfully request that the instant rejection be withdrawn.

Item 10. Claims 44, 46 and 49 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Zhang et al. as applied to claim 1, and further in view of U.S. Patent No. 5,814,666 (“Green et al.”) and Japanese Laid-Open Application No. JP 08-092051 A (“Yamamoto et al.”). The Examiner submits that it would have been obvious to one of ordinary skill in the art at the time of the invention to use the zeolite disclosed by Zhang et al. in the carrier containing a deodorizing cosmetic composition disclosed by Yamamoto et al. as motivated by the teaching of Green et al. that materials capable of releasing nitric oxide exhibit antimicrobial functionality.

As stated in the recently published Examination Guidelines for Determining Obviousness, “the Supreme Court reaffirmed the familiar framework for determining obviousness as set forth in *Graham v. John Deere Co.*...” (Examination Guidelines for Determining Obviousness Under 35 U.S.C § 103 in View of the Supreme Court Decision in *KSR International Co. v. Teleflex Inc.* Federal Register Vol. 72, No. 195, 57526-57535, 57526). Hence, and as long established under that framework, to establish a *prima facie* case of obviousness, three requirements must be satisfied (M.P.E.P. § 2143). First, the prior art relied upon, coupled with the knowledge generally available in the art at the time of the invention, must contain some suggestion or incentive that would have motivated the skilled artisan to modify a reference or to combine references. *In re Oetiker*, 24 U.S.P.Q.2d 1443, 1446 (Fed. Cir. 1992); *In*

re Fine, 837 F.2d at 1074; *In re Skinner*, 2 U.S.P.Q.2d 1788, 1790 (Bd. Pat. App. & Int. 1986). Second, the proposed modification or combination of the prior art must have a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. *See Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1209, 18 U.S.P.Q.2d 1016, 1023 (Fed. Cir. 1991). Third, the prior art reference or combination of references must teach or suggest all of the limitations of the claims. *See In re Wilson* 424 F.2d 1382, 1385, 165 U.S.P.Q. 494, 496 (CCPA 1970) (“All words in a claim must be considered in judging the patentability of that claim against the prior art”).

As discussed above, the prior art reference or references when combined must teach or suggest *all* the recitations of the claims, and there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. M.P.E.P. § 2143. The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. M.P.E.P. § 2143.01, citing *In re Mills*, 916 F.2d 680, 16 U.S.P.Q.2d 1430 (Fed. Cir. 1990). As emphasized by the Court of Appeals for the Federal Circuit, to support combining references, evidence of a suggestion, teaching, or motivation to combine must be clear and particular, and this requirement for clear and particular evidence is not met by broad and conclusory statements about the teachings of references. *In re Dembiczak*, 50 U.S.P.Q.2d 1614, 1617 (Fed. Cir. 1999). In an even more recent decision, the Court of Appeals for the Federal Circuit has stated that, to support combining or modifying references, there must be particular evidence from the prior art as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed. *In re Kotzab*, 55 U.S.P.Q.2d 1313, 1317 (Fed. Cir. 2000). Lastly, the teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not in Applicant’s disclosure. *In re Vaeck*, 947 F.2d 468, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991).

As set forth in the discussion regarding Items 4 and 5 hereinabove, The disclosures of Zhang et al. do not teach all the elements of claim 1 as amended herein. Of question therefore, is whether the combination of the disclosures of Zhang et al., Green et al. and Yamamoto et al.

teach all the elements of that which is instantly claimed, or provide the teaching, motivation and suggestion required to allow one of ordinary skill in the art arrive at that which is instantly claimed without impermissible hindsight of Applicants' disclosure.

The Examiner alleges that the teaching of Green et al. that materials capable of releasing nitric oxide exhibit antimicrobial activity and the teaching of Yamamoto et al. of a composition comprising an antimicrobial zeolite and a cosmetic carrier provide the necessary teaching, suggestion and motivation to combine the disclosures of Green et al. and Yamamoto et al. with the zeolite of Zhang et al. in order to arrive at the composition of the instant claims. Applicants respectfully disagree.

The Supreme Court has articulated that obviousness under § 103(a) is determined by an analysis of the following factors: (1) the scope and content of the prior art; (2) the differences between the prior art and the claims at issue; (3) the level of ordinary skill in the art at the time the invention was made; and (4) objective evidence of nonobviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966). The obviousness or nonobviousness of the subject matter is to be determined based on these considerations however, secondary considerations such as commercial success, long-felt but unresolved needs and the failure of others can be utilized to determine the circumstances surrounding the origin of the invention. *See KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1730 (2007). If such secondary considerations exist, they must be considered. *See Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538-1539 (Fed. Cir. 1983).

In *KSR*, the Supreme Court also made clear that predictable variations are likely obvious, but unpredictable variations are not:

If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability. For the same reason, if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill. *Sakraida* and *Anderson's-Black Rock* are illustrative - a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions.

KSR at 1740.

The Court also recognized that when the prior art taught away from the claimed invention, the invention was more likely to be non-obvious: “when the prior art teaches away from combining certain known elements, discovery of a successful means of combining them is more likely to be nonobvious.” *KSR* at 1740 (citing *United States v. Adams*, 383 U.S. 39, 51-52 (1996)).

The Court also emphasized the importance of identifying “a reason” that a person of ordinary skill in the relevant field would have combined the elements in the fashion claimed by the new invention. *Id.* at 1731. The Court also emphasized that this analysis should be made explicit:

Often it will be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. To facilitate review, this analysis should be made explicit.

Id. at 1740-1741 (citing *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)).

As amended herein, claim 1 incorporates the subject matter of previously presented claim 44. As such, the following remarks relate to the patentability of currently amended claim 1 as well as to the claims 44, 46 and 49 as discussed in Item 10 by the Examiner.

Zhang et al. describe removal of nitrogen monoxide on copper ion-exchanged copper ion-exchanged zeolites by pressure swing adsorption (PSA). Zhang et al. point out that adsorbents for PSA must possess high capacity for reversible adsorption of nitric oxide (*see*, Introduction, second paragraph of Zhang et al.). However, while Zhang et al. may broadly discuss reversible adsorption of nitric oxide on zeolites, the release of nitric oxides from the zeolites described by Zhang et al. was analyzed by temperature-programmed desorption (TPD) techniques (*see*, Abstract) and desorption of nitric oxide from the zeolites described by Zhang et al. shows desorption peaks of nitric oxide (NO) are exhibited at 400, 463 and 663 K (127, 190 and 390 °C respectively). As one of skill in the art will appreciate, while it may be possible to desorb nitric

oxide from the zeolites discussed by Zhang et al. the temperatures and conditions required to desorb nitric oxide from the zeolites of Zhang et al. are clearly NOT suitable for releasable binding and delivery of nitric oxide from said zeolites and use in surgery and/or therapy. As such, Zhang et al. clearly do not describe or envision a zeolite comprising reversibly bound nitric oxide that may be used in surgery and/or therapy of the present invention.

Green et al. describe compositions capable of releasing nitric oxide and therapeutic methods of use thereof for the treatment of microorganism-related disease states (*see*, Abstract of Green et al.). Particularly indicated compositions are nitric oxide generators encapsulated in liposomes. However, while Green et al. may propose that compositions that can deliver and release nitric oxide that may be used as antimicrobials, as one of skill in the art will appreciate, Green et al. provide no teaching or suggestion, with a reasonable expectation of success, that compositions comprising zeolites comprising releasably adsorbed nitric oxide might be prepared and used as antimicrobials.

Yamamoto et al. describe a cosmetic composition comprising an antimicrobial zeolite and silicone (*see*, Abstract of U.S. Patent No. 5,723,110, the U.S. counterpart to JP 08-092051 A). The antimicrobial zeolite described by Yamamoto et al. have all or part of its ion exchangeable ions substituted by ammonium ions and antibacterial metal ions. Yamamoto et al. provide a list of examples of antibacterial metal ions envisioned (*see*, col. 3, lines 14–16). However, while the disclosures of Yamamoto et al. may generally discuss an antimicrobial zeolite comprising ion-exchanged antimicrobial metal ions and a silicone (cosmetic) carrier, Yamamoto et al. also do not provide a disclosure that would suggest or enable one of ordinary skill in the art to prepare an antimicrobial zeolite comprising reversibly bound nitric oxide and a cosmetic carrier. Furthermore, Yamamoto et al. are silent regarding a composition comprising a zeolite and pharmaceutical and nutraceutical carriers.

A zeolite comprising releasably/reversibly bound nitric oxide suitable for use in pharmaceutical, nutraceutical and cosmetic applications would require that the nitric oxide exhibit releasability at ambient and/or physiological temperatures and conditions. As discussed above, the temperatures and conditions required for the desorption of nitric oxide from the zeolites of Zhang et al. (at least 127 °C) exceed the temperature for boiling water. As one of skill

in the art will appreciate, the zeolites as described and envisioned and described by Zhang et al. do not exhibit nitric oxide releasability under ambient and/or physiological conditions and are thus not appropriate for such uses. While Green et al. discuss compositions comprising releasably/reversibly bound nitric oxide encapsulated in liposomes for use as antimicrobials, Green et al., alone or in combination with Zhang et al., do not teach or suggest that nitric oxide may be reversibly/releasably bound on zeolites that may be used as antimicrobials, let alone in surgery and/or therapy, and do not provide the teaching, motivation or suggestion to enable one of ordinary skill in the art to prepare a composition comprising a zeolite comprising releasably/reversibly bound nitric oxide for use in surgery and/or therapy. Similarly, while Yamamoto et al. discuss a composition comprising an antibacterial zeolite comprising ion-exchanged antimicrobial metal ions and a cosmetic carrier, Yamamoto et al., alone or in combination with Zhang et al. and Green et al. do not teach or suggest that an antimicrobial zeolite may comprise releasably bound nitric oxide, and not provide the teaching, motivation or suggestion to enable one of ordinary skill in the art to prepare a composition comprising a zeolite comprising releasably/reversibly bound nitric oxide for use in surgery and/or therapy, further comprising a cosmetic carrier.

Nevertheless, Applicants amend claim 44 herein to point out that the composition of claim 1 may be contained in an airtight bag and add new claims 50–52, that are more particularly directed to a composition comprising the zeolite of the invention and a pharmaceutical carrier, the zeolite of the invention and a nutraceutical carrier and the zeolite of the invention and a cosmetic carrier. The disclosures of Zhang et al., Green et al. and Yamamoto et al. are silent regarding the composition of claim 1 contained in an airtight bag, the composition of claim 1 wherein the carrier is a pharmaceutical carrier and the composition of claim 1 wherein the carrier is a nutraceutical carrier.

In view of the foregoing remarks, Applicants respectfully submit that Zhang et al., Green et al. and Yamamoto et al., alone or in combination, do not teach or suggest all the elements of the instantly claimed composition. Furthermore, the reference disclosures and the knowledge in the prior art at the time of the invention do not provide the necessary teaching, motivation and suggestion that would enable one of ordinary skill in the art, with a reasonable expectation of

success, to arrive at the instantly claimed composition without the use of impermissible hindsight of the disclosures of the present application. As such, Applicants respectfully request that the instant rejection be withdrawn.

Item 11. Claims 45, 47 and 48 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Zhang et al. as applied to claim 1 above, and in further view of Green et al. and PCT International Publication No. WO 00/64506 A1¹ (Barry et al.). The Examiner submits that it would have been obvious to one of ordinary skill in the art at the time of the invention to utilize the zeolite of Zhang et al. in the stent described by Barry. The Examiner alleges that one of ordinary skill in the art would have been motivated by the teachings of Green et al. that materials capable of releasing nitric oxide exhibit antimicrobial activity, the disclosures of Zhang et al. describing a zeolite having the capability to release adsorbed nitric oxide and the teaching of Barry that antimicrobial zeolites may beneficially be included in stents.

As discussed above regarding Item 10, while Green et al. may set forth that materials (i.e., liposomes) capable of releasing nitric oxide may exhibit antimicrobial activity and the disclosures of Barry et al. may set forth that antimicrobial zeolites may be used with stents, Green et al. do not teach how to make, with a reasonable expectation of success, an antimicrobial zeolite capable of releasing nitric oxide. While Barry et al. may teach a stent comprising an antimicrobial zeolite, the antimicrobial zeolites discussed by Barry et al., as with those discussed by Yamamoto et al., are envisioned to comprise ammonium ions or metal ions, e.g., silver, that exhibit antimicrobial characteristics (*see*, page 12, lines 6–17 of Barry et al.). Barry et al., as with Green et al., do not provide the teaching, suggestion or motivation, with a reasonable expectation of success, to prepare an antimicrobial zeolite comprising releasably bound nitric oxide. As discussed hereinabove regarding Item 10, it will be apparent to one of skill in the art that the zeolites of Zhang et al. do not describe or envision a zeolite comprising reversibly bound nitric oxide that may be used/is suitable for use in surgery and/or therapy. Neither Green et al. nor Barry et al. provide the necessary disclosures that allow one of ordinary skill in the art to arrive at the subject matter of the instant claims.

¹ Applicants note that the Examiner cites Barry et al. as U.S. 00/64506 A1 as opposed to a PCT publication. Applicants believe that this was an inadvertent oversight.

Attorney Docket No. 9013-72
In re: Morris et al.
Application Serial No.: 10/562,401
Filed: April 5, 2006

In view of the foregoing remarks, Applicants submit that Zhang et al., Green et al. and Barry et al., alone or in combination, do not teach all the elements of that which is instantly claimed. Furthermore, the reference teachings and the knowledge in the prior art at the time of the invention do not provide the necessary teaching, motivation and suggestion that would enable one of ordinary skill in the art, with a reasonable expectation of success, to arrive at the instantly claimed composition without the use of impermissible hindsight of the disclosures of the present application. As such, Applicants respectfully request that the instant rejection be withdrawn.

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CONCLUSION

Accordingly, Applicants submit that the present application is in condition for allowance and the same is earnestly solicited. Should the Examiner have any small matters outstanding of resolution, he is encouraged to telephone the undersigned at 919-854-1400 for expeditious handling.

A Request for Continued Examination (RCE) is included with this response. Applicants hereby authorize the Commissioner to charge Deposit Account No. 50-0220 in the amount of \$810.00 for the RCE. Applicants believe this amount to be correct; however, should any extension of time be required for the filing of this paper, Applicants respectfully request that this be considered a petition therefor. The Commissioner is hereby authorized to charge any deficiency or credit any overpayment to Deposit Account No. 50-0220.

Respectfully submitted,



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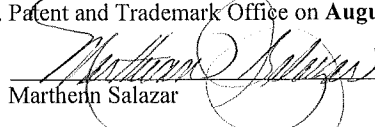
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CERTIFICATION OF TRANSMISSION

I hereby certify that this correspondence is being transmitted via the Office electronic filing system in accordance with § 1.6(a)(4) to the U.S. Patent and Trademark Office on **August 6, 2010**.

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